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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,995	02/02/2006	Jean-Jacques Zeiller	MERCK3129	2593
23599 7590 03/20/2009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER				
ZUCKER, PAUL A				
ART UNIT		PAPER NUMBER		
1621				
MAIL DATE		DELIVERY MODE		
03/20/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/566,995

Applicant(s)

ZEILLER ET AL.

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S5108)
Paper No(s)/Mail Date 2/2/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-8 and 14 in the reply filed on 29 December 2008 is acknowledged. Claim 14 was included by clerical error in this group. The traversal is on the ground(s) that the claims of Groups II-VI, drawn to processes of making the compounds of formula I and to processes of using them, should be maintained in a single application, as explained in Annex B of the PCT rules. Annex B of the PCT rules clearly states that unity of invention "*shall* be found where claims are directed to a product, a process specially adapted for making that product, and a process specially adapted for using that product. This is not found persuasive because the source of unity in these claims can derive only from a special technical feature provided by the compounds. The compounds, however, are not novel, as demonstrated by the prior art cited below, and cannot provide the special technical feature required for unity of invention.

The requirement is still deemed proper and is therefore MADE FINAL. Claims 8-13 and 15 are held withdrawn from consideration as being drawn to a non-elected invention. Claim 14, as a product-by-process claim will be assessed for patentability without consideration of the process.

Information Disclosure Statement

2. The information disclosure statement filed 2 February 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign

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patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds of formula (I), does not reasonably provide enablement for their solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not

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satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- a. the breadth of the claims: In the instant case the claims are drawn to a broad variety of compounds containing a large number of different compounds in which may or may not readily form crystals. Among those that do crystallize, each has its own crystalline habit
- b. the nature of the invention: The instantly claimed invention involves the crystallization of a large variety of structures. As such, it is highly unpredictable since one of ordinary skill in the art cannot determine *a priori* which crystallize and among those that do, which can form solvates or not.
- c. the state of the prior art: The crystallization of compounds is unpredictable and requires individual experimentation with each novel compound in order to determine if it crystallizes, and, if so, if it will form solvates with any of a large variety of solvents.
- e. the amount of direction provided by the inventor: The inventor provide no direction for the formation of any solvate with a compound of the invention
- f. the existence of working examples: The no working examples are provided for the formation and or use of solvates.

Based upon the analysis above, the Examiner concludes that undue experimentation is required to make and use the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 5, 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The enumerated claims recite the limitation "preferably" in various locations. It is therefore impossible to determine the metes and bounds of Applicants' claimed invention since the claims encompass undefined, less preferable identities. Claim 2, 5, 6 and 7 are therefore rendered indefinite.
5. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The enumerated claims recite the limitation "derivatives" in various locations. It is therefore impossible to determine the metes and bounds of Applicants' claimed invention since the claims encompass undefined compounds. For example, can carbon dioxide be considered a derivative since the claimed compounds may be burned to produce it? Claims 1- 7 are therefore rendered indefinite.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

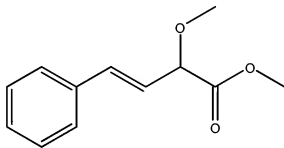
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by He et al (Journal of the American Chemical Society, Enantioselective Synthesis of a Novel Trans Double Bond Ceramide Analogue via Catalytic Asymmetric Dihydroxylation of an Enyne. The Role of the Trans Double Bond of Ceramide in the Fusion of Semiliki Forest Virus with Target Membranes, 1999, 121(16), pages 3897-3903). He discloses (Page 3902, column 1, lines 1-5) the compound **5a** which corresponds to an instantly claimed compound of formula (I) in which R^1 , $R^2 = H$ and $R^3 = p$ -methoxyphenyl. The Examiner considers the methoxy-substituted phenyl to correspond to a pharmaceutically acceptable derivative of the unsubstituted phenyl. He discloses (Page 3899, column 1, Scheme I) ethyl acetate-hexane solutions of the compound which the Examiner deems to correspond to a pharmaceutical composition. He therefore anticipates claims 1-4, 6 and 14.
7. Claims 1, 3-8 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies et al (Tetrahedron Letters, Regiochemistry of Molybdenum-catalyzed O-H Insertions of Vinylcarbenoids, 2000, 41, pages 4851-4854). Davies discloses (Page 4852, center, figure 1) the compound **5a** which corresponds to an instantly claimed compound of formula (I) in which

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R^1 = methyl, R^2 = H R^3 = H and R = t-butyl in methanol solution. The Examiner considers this to correspond to a pharmaceutical composition. Davies also discloses (Page 4853, Table 1, first row) a methanol solution of the compound **8a**:



which the Examiner deems to correspond to a pharmaceutical composition of the first-listed compound in instant claim 8. Davies therefore anticipates claims 1, 3-8 and 14.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761

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(CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-7 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,465,752-B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed compounds correspond to adjacent lower homologues of those claimed in the patent. One of ordinary skill in the art would therefore have had a reasonable expectation that the instantly claimed compounds would have activity similar to that displayed by the compound and been motivated to perform the instantly claimed invention. Thus the instantly claimed invention would have been obvious to one of ordinary skill in the art.

Conclusion

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9. Claims 1-15 are pending. Claims 1-8 and 14 are rejected. Claims 8-13 and 15 are held withdrawn from consideration as being drawn to a non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Paul A. Zucker/

Primary Examiner, Art Unit 1621